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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,872	12/04/2000	Tony Wai-Chiu So	A33477 PCT U	5826
20350	7590	05/14/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			GOLLAMUDI, SHARMILA S	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/673,872

Applicant(s)

WAI-CHIU SO ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 8-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Receipt of the Amendments, Applicant's Remarks, and Extension of Time received on February 24, 2004 and the Information Disclosure Statement received on December 22, 2003 is acknowledged. Claims **1-6 and 8-24** are pending in this application. Claims 7 and 25 stand cancelled.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**The rejection of claims 1-6, 8-9, 12-19, and 21-23 under 35 U.S.C. 103(a) as being unpatentable over Kasting et al (5,041,439) by itself or in view of Yu et al (5,156,836) or WO 97/12602 is maintained.**

Kasting et al teaches a minoxidil acid salt made from an acid such as hydrochloric acid, acetic acid, or lactic acid (col. 6, lines 44-53). Kasting teaches utilizing 0.1-10% of the active. Water (0-90%), isopropanol, isopropyl alcohol, ethanol (0-85%),

Art Unit: 1616

or mixtures thereof are taught as solvents. Composition XIV contains 12% active, 54% 1,2 6-hexanetriol, oleyl alcohol, and 30% ethanol (Note composition XIV). Preferred triols are glycerol and 1,2,6 hexanetriol. Kasting teaches the amount of active also depends on factors such as the severity of the condition, the cause of the condition, the specific active used, etc. (col.7, lines 5-15). Kasting teaches several formulations such as shampoo, gel, mousse, etc.

Kasting et al do not exemplify the minoxidil acid salt.

Yu et al teaches a therapeutic composition for hair loss that contains minoxidil (2%), water, ethanol, propylene glycol (16%), and lactic acid (Note example 3). Yu et al teaches the active agent in the range of .01-40% (col.6, lines 51-53). Further, Yu teaches the volume ratio of ethanol: water: propylene glycol to be 40:40:20 (col. 7, lines1-3). The composition is applied to the scalp to treat hair loss (Note example 3). Yu teaches lactic acid helps dissolve minoxidil.

WO teaches a topical composition for minoxidil. WO discloses that making materials more hydrophilic, improves penetration through the hair follicle. Minoxidil is modified by reacting it with an organic acid such as lactic acid. See page 4.

Although Kasting et al does not exemplify the addition of the organic salt, it is obvious that the acid is added to form the acid salt derivative of the minoxidil from the teachings on column 6, and it is the amount used is effective to allow the active to become more hydrophilic or soluble.

It would have been obvious to one of ordinary skill in the art at the time the invention was made look to the teachings of Yu et al or WO and utilize the instant acid

derivative. One would be motivated to do so since both references teach that by adding salt to minoxidil, it yields a more soluble form of the active. Further, WO teaches this addition to yield a hydrophilic compound, allows for better penetration into the hair follicles.

### ***Response to Arguments***

Applicant argues that Kasting et al teach away from the instant amount of the co-solvent (polyhydric alcohols) and the examples on column 11 012 utilize an amount of 30-97.75%. Applicant argues that Kasting et al require a mixture of a diol or triol and a polar lipid alcohol.

Applicant argues that Yu does not cure this deficiency since Yu teaches 15 to 16% of polypropylene glycol. Applicant argues that Weiner requires the minoxidil encapsulated in lipid vesicles and instant invention does not require the lipid vesicle. Thus, there is not motivation to not encapsulate the minoxidil in a lipid vesicle as seen in instant invention.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, the examiner points out that the claims are rejected under 103(a) obviousness, thus the reference merely has to suggest the instant invention. Clearly, Kasting teaches the instant amount of the co-solvent on column 8, lines 8-9 wherein Kasting states that the composition contains about 5 to 99.99% of the diol or triol compound and polar lipid compound mixture. This range still falls within applicant's range of "less than 10%." Secondly, although it is acknowledged that the examples in Kasting contain a higher amount of the co-solvent, disclosed examples and preferred embodiments do not

constitute a teaching away from the broader disclosure or nonpreferred embodiment. See *In re Susi*. Further, the manipulation of concentrations through routine experimentation and from the guidance of the prior art is deemed to be an obvious parameter within the skill of the art. Therefore, it is deemed that Kasting's range falls within the parameters of obviousness absent unexpected data demonstrating the criticality of the instant concentrations.

In regards to other components in the composition, the examiner points out that the instant claim language allows for the incorporation of other components. The claim language "consisting of" excludes the components that the applicant argues against.

Lastly in regards to the secondary references, it is pointed out that these references (Yu and Weiner) are relied upon for their specific teaching of the instant minoxidil salt. Thus, the secondary references are not relied upon for their teaching of the broad aspect of the claims since the primary reference teaches this and only lacks in the specific exemplification of the instant salts. Thus, the examiner does not need to provide for a motivation to exclude a lipid vesicle since this is not the embodiment that Weiner is relied upon for. However for arguendo sake though, it is pointed out that the claims do not exclude a lipid vesicle.

It should be noted that claim 20 only recites that the claims can only have less than 10% of propylene glycol; however this does not exclude the composition from having high concentrations of other diols and triols such as glycerol. Thus, Kasting's examples teach the limitations of this claim.

Art Unit: 1616

**The rejection of claims 10-11, 20, and 24 under 35 U.S.C. 103(a) as being unpatentable over Kasting et al (5,041,439) by itself or in view of Yu et al (5,156,836) or WO 97/12602 in further view of Uchikawa et al (5,156,836) is maintained.**

As set forth above, Kasting et al teaches a minoxidil acid salt made from an acid such as hydrochloric acid, acetic acid, or lactic acid (col. 6, lines 44-53). Water (0-90%), isopropanol, isopropyl alcohol, ethanol (0-85%), or combinations thereof are taught as solvents. Yu et al and WO teach utilizing organic acids to solubilize minoxidil.

The references do not teach the use of benzyl alcohol.

Uchikawa et al teaches a hair tonic that contains an active agent such as minoxidil, organic acids such as lactic acid, water, polyhydric alcohols such as glycerin or propylene glycol, and alcohols such as ethanol, isopropanol alcohol, or benzyl alcohol. See column 4.

It would have been obvious at the time the invention was made to look at Uchikawa and substitute ethanol with benzyl alcohol. One would be motivated to do so since Uchikawa teaches the functional equivalency of ethanol, isopropanol and benzyl alcohol in a composition. Further, one would expect similar results since Kasting teaches the use of ethanol or isopropanol in the composition. Therefore, a skilled artisan would expect similar results by utilizing either alcohol in the composition.

### ***Response to Arguments***

Applicant argues that Uchikawa does not teach the instant minoxidil in examples and teaches the use of other components.

Applicant's arguments have been fully considered but they are not persuasive. As pointed out above, the examiner relies on Uchikawa for its specific teaching of benzyl alcohol and its teachings of the functional equivalence of ethanol, isopropanol, and instant benzyl alcohol. Kasting et al teach the broad nature of the instant invention and therefore Uchikawa need not exemplify a minoxidil composition since this is not the embodiment that Uchikawa is relied upon for.

**The rejection of claims 1-6, 8-9, 12-19, and 21-23 under 35 U.S.C. 103(a) as being unpatentable over Bazzano (5183817) in view of in view of Yu et al (5,156,836) or WO 97/12602 is maintained.**

Bazzano teaches a minoxidil cream containing retinoic acid, minoxidil (.5-5%), ethanol, propylene glycol (5-50%), and distilled water (up to 10%). Formulation example II contains 1% retinoic acid, 10% minoxidil, 4% cetyl alcohol, 4% ethanol, and up to 100% water. Bazzano teaches the use of pharmaceutically acceptable acid salt. See column 19, lines 1-25. Bazzano discloses that a major problem in influencing hair growth is obtaining good percutaneous absorption of the active compounds. The retinoid compounds cause excellent absorption of the hair follicles. See column 19, lines 35-40. The formulation can contain any pharmaceutically acceptable carrier, additive, or solubilizer.

The reference does not specify the pharmaceutically acceptable salt.

Yu et al teaches a therapeutic composition for hair loss that contains minoxidil (2%), water, ethanol, propylene glycol (16%), and lactic acid (Note example 3). Yu et al teaches the active agent in the range of .01-40% (col.6, lines 51-53). Further, Yu



Art Unit: 1616

teaches the volume ratio of ethanol: water: propylene glycol to be 40:40:20 (col. 7, lines 1-3). The composition is applied to the scalp to treat hair loss (Note example 3). Yu teaches lactic acid helps dissolve minoxidil.

WO teaches a topical composition for minoxidil. WO discloses that making materials more hydrophilic, improves penetration through the hair follicle. Minoxidil is modified by reacting it with an organic acid such as lactic acid. See page 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made look to the teachings of Yu et al or WO and utilize the instant acid derivative. One would be motivated to do so since both references teach that by adding salt to minoxidil, it yields a more soluble form of the active. Further, WO teaches this addition to yield a hydrophilic compound, allows for better penetration into the hair follicles. Further, since Bazzano is concerned with penetration of the composition into the hair follicle one would expect an additive effect of increasing penetration of the composition by adding instant salt. Lastly, Yu et al and WO demonstrate that it is known in the art to add a salt to increase solubility of an insoluble active.

### ***Response to Arguments***

Applicant argues that Bazzano teaches the criticality of the combination of minoxidil and retinoid. Therefore, the prior art teaches away from the instant invention since it incorporates retinoid in the composition. The merits of Weiner and Yu are argued.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points out that the instant claim language "comprising" does not exclude

Art Unit: 1616

the use of a retinoid and therefore it is irrelevant that Bazzano incorporates a retinoid in the composition. The claim language "consisting of" excludes the components that the applicant argues against.

The merits of Weiner and Yu have been addressed above. The secondary references are specifically utilized for the instant salts since the primary reference teaches the broad aspect of the instant invention.

**The rejection of claims 10-11, 20, and 24 under 35 U.S.C. 103(a) as being unpatentable over Bazzano (5,183,187) in view of Yu et al (5,156,836) or WO 97/12602 in further view of Uchikawa et al (5,156,836) is maintained.**

As set forth above, Bazzano teaches a minoxidil cream containing retinoic acid, minoxidil (.5-5%), ethanol, propylene glycol (5-50%), and distilled water (up to 10%). Yu et al and WO teach utilizing organic acids to solubilize minoxidil.

The references do not teach the use of benzyl alcohol.

Uchikawa et al teaches a hair tonic that contains an active agent such as minoxidil, organic acids such as lactic acid, water, polyhydric alcohols such as glycerin or propylene glycol, and alcohols such as ethanol, isopropanol alcohol, or benzyl alcohol. See column 4.

It would have been obvious at the time the invention was made to look at Uchikawa and substitute ethanol with benzyl alcohol. One would be motivated to do so since Uchikawa teaches the functional equivalency of ethanol, isopropanol and benzyl alcohol in a composition. Therefore, a skilled artisan would expect similar results by utilizing either alcohol in the composition.

***Response to Arguments***

Applicant argues that Uchikawa does not teach the instant minoxidil in examples and teaches the use of other components.

Applicant's arguments have been fully considered but they are not persuasive. As pointed out above, the examiner relies on Uchikawa for its specific teaching of benzyl alcohol and its teachings of the functional equivalence of ethanol, isopropanol, and instant benzyl alcohol.

**The rejection of claims 1-6, 8-9, 12-19, and 21-23 under 35 U.S.C. 103(a) as being unpatentable over WO 97/03638 in view of WO 97/12602 is maintained.**

WO teaches a hair care composition containing 0.1-7% minoxidil, 0.1-5% cyclodextrin, 0.5-15% of a minoxidil solvent (propylene glycol), 30-50% monoalcohol (ethanol or isopropanol), and water. Note abstract and examples.

WO 97/03638 does not teach the use of lactic or acetic acid or teach the instant formulation.

WO teaches a topical composition for minoxidil. WO discloses that making materials more hydrophilic, improves penetration through the hair follicle. Minoxidil is modified by reacting it with an organic acid such as lactic acid. See page 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of WO 97/03638 and WO 97/12602 and utilize the instant acids. One would be motivated to do so since WO teaches that organic acids modify minoxidil to yield a hydrophilic active and therefore is more soluble in water and improves penetration into the hair follicle. Therefore, one would be

Art Unit: 1616

motivated to add an organic acid to increase minoxidil's solubility in water and improve its penetration.

### ***Response to Arguments***

Applicant argues that Navarro et al (WO 97/03638) utilizes gamma-cyclodextrin and does not teach disclose decreasing the percentage of polyhydric alcohol without replacing it with gamma-cyclodextrin. Therefore, it is argued that instant invention does not require or utilize Navarro's cyclodextrin. The merits of Weiner's lipid vesicle are argued.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points out that the instant claim language "comprising" does not exclude the use of gamma-cyclodextrin and therefore it is irrelevant that Navarro et al incorporates cyclodextrin in the composition. The claim language "consisting of" excludes the components that the applicant argues against.

The merits of Weiner have been addressed above.

**The rejection of claims 10-11, 20, and 24 under 35 U.S.C. 103(a) as being unpatentable over WO 97/03638 in view of WO 97/12602 in further view of Uchikawa et al (5,156,836) is maintained.**

As set forth above, WO teaches a hair care composition containing 0.1-7% minoxidil, 0.1-5% cyclodextrin, 0.5-15% of a minoxidil solvent (propylene glycol), 30-50% monoalcohol (ethanol or isopropanol), and water. Note abstract and examples. WO teaches utilizing organic acids to solubilize minoxidil.

The references do not teach the use of benzyl alcohol.

Uchikawa et al teaches a hair tonic that contains an active agent such as minoxidil, organic acids such as lactic acid, water, polyhydric alcohols such as glycerin or propylene glycol, and alcohols such as ethanol, isopropanol alcohol, or benzyl alcohol. See column 4.

It would have been obvious at the time the invention was made to look at Uchikawa and substitute ethanol with benzyl alcohol. One would be motivated to do so since Uchikawa teaches the functional equivalency of ethanol, isopropanol and benzyl alcohol in a composition. Therefore, a skilled artisan would expect similar results by utilizing either alcohol in the composition.

### ***Response to Arguments***

Applicant argues that Uchikawa does not teach the instant minoxidil in examples and teaches the use of other components.

Applicant's arguments have been fully considered but they are not persuasive. As pointed out above, the examiner relies on Uchikawa for its specific teaching of benzyl alcohol and its teachings of the functional equivalence of ethanol, isopropanol, and instant benzyl alcohol.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

Art Unit: 1616

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-242-0614. The examiner can normally be reached on M-F (8:00-5:00) with alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SSG

May 5, 2004

  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER